Bhattacharya R, Birdsall PD, et al. A Randomized Controlled Trial of Knifelight and Open Carpal Tunnel Release. J Hand Surg Br. 2004; 29B(2): 113-115.

Design: Randomized crossover trial

Population/sample size/setting:

- 26 patients (18 women, 8 men, mean age 48) operated on for bilateral CTS at an orthopedic department in the UK
- All were referred by a single hand surgeon who had determined that they had classical CTS which warranted surgical release

Main outcome measures:

- Both hands were operated on, one with open carpal tunnel release, the other with Knifelight, a device which transilluminates the wrist and allows a blind division of the flexor retinaculum to be made with a small incision
- The hand with the more severe symptoms was operated first, with the second hand operated 6 weeks later
- Randomization was to which technique was used to operate on the first wrist (n not stated for how many wrists first had Knifelight or open release)
- Original study enrollment was of 32 patients, of which 6 were excluded from the analysis: three declined to have the second operation after experiencing good relief from the first procedure (2 open release and 1 Knifelight); one had to have Knifelight procedure converted to open release after the Knifelight broke during the first procedure; one reported complete relief of the unoperated hand and declined a second operation, and one failed to attend the follow-up evaluation after the second operation
- Median time to return to work was 2 weeks for both Knifelight and open release
- Level of relief of symptoms at 2 weeks and at 6 weeks was not different between Knifelight
- Scar tenderness was reported for only 8 of the 26 Knifelight operations, but was reported in 17 of 26 open operations
- Patients were evenly divided about their preference of operation: 13 thought the Knifelight was better, and 13 preferred the open procedure

Authors' conclusions:

- No significant advantage appears to be associated with Knifelight
- Knifelight is a single-use instrument, and is expensive; the cost will be greater than for an open procedure
- Nothing can be said about the safety of the Knifelight
- Having the patient act as his or her own control increases internal validity of the study and reduces required sample size
- Knifelight cannot be recommended in the absence of a clear advantage over the open procedure

Comments:

- Most of the attrition appears to have occurred for reasons that do not affect the validity of the study; since the more symptomatic side was operated on first, the fact that the second operation was not performed would not be expected to bias the results
- The number of wrists which had Knifelight in the first procedure is not clearly stated, but should be about 13 if the randomization produced exactly balanced groups
- If the randomization did not produce exactly equal numbers of first procedures by Knifelight and open release, the lack of a difference in measured outcome could be difficult to interpret (i.e., if more Knifelight procedures were done on the more problematic wrist, a possible advantage of Knifelight could be missed; if more open procedures were done on that wrist, a possible disadvantage of the Knifelight could be missed)
- The 2.5 cm incision for the open procedure is about half the length of a classic incision for open release, and may have decreased the difference between it and the Knifelight
- The advantage of the Knifelight in having less scar tenderness could potentially be associated with other benefits in future studies, but the conclusion that it has no clear additional benefit is reasonable based on the available data

Assessment: Adequate to support a statement that there is some evidence that Knifelight does not offer functional or symptomatic advantages over the open procedure